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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/154,283 09/16/98 MOO-YOUNG

A CBR-3.0-016

HM12/1216  
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EXAMINER

MOEZIE, M

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

12/16/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/154,283**

Applicant(s)  
**Moo-Young**

Examiner  
**M. MOEZIE**

Group Art Unit  
**1617**



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-44 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-44 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1617

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-37 and 42-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/154,287. Although the conflicting claims are not identical, they are not patentably distinct from each other because the male contraceptive compositions and dosage forms broadly claimed herein clearly encompass and render obvious the particular known type of transdermal dosage form claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-21 and 38-41 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-15 of copending Application No. 09/154,287. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

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The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: male contraceptive and/or androgen replacement treatments employing non-5-alpha reducible androgens.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Sundaram et al.

(AR).

See column 2, paragraph 1 on page 202.

Claims 1-34 and 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundaram et al. (AR).

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The prior art teaches that androgen replacement and/or reversible male contraceptive methods, compositions and dosage forms employing one of the preferred non-5-alpha reducible androgens herein, are known in the art. See, e.g., the abstract and page 202, column 2, paragraph 1 therein.

The instant claims differ primarily in that they are drawn to amounts of androgen which bring gonadotropin and testosterone levels to below specified levels, , to the treatment of non-sterile males and to androgen replacement therapies which do not cause sterility.

One of ordinary skill would have found it obvious to optimize the amount of androgen administered to control fertility since administration of the preferred androgen herein is known to control hormone levels and thereby influence fertility or sterility. See, e.g., page 201, columns 1-2 under "Biopotency of MENT".

Further, the instant method of controlling gonadotropin and testosterone levels in order to influence fertility in a male would be reasonably expected to be useful in non-sterile<sup>males</sup> as well as males rendered reversibly sterile by chemical means, absent evidence to the contrary.

Additionally, the optimization of amounts of androgen administered to those effective in replacement therapy but which do not induce sterility in hosts is considered within the skill of the artisan, absent evidence to the contrary.

The employment of known active agents in pharmaceutical compositions with carrier materials or excipients is considered within the skill of the artisan.

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The employment of particular known pharmaceutical dosage forms for the administration of a known active agent is considered within the skill of the artisan.

Finally, the optimization of a dosage regimen for the administration of a known active is also considered within the skill of the artisan.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Moezie whose telephone number is (703) 308-4612.

The examiner can normally be reached on Monday to Friday from 9:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph. D., can be reached on (703) 308-1235. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

MOEZIE:tcj  
December 9, 1999

  
MINNA MOEZIE  
PRIMARY EXAMINER